U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Immunizations & Response Management
Prototype Use Case
August 31st, 2007

Table of Contents

List of Figures

1.0 Preface

Use cases developed for the American Health Information Community (AHIC) are based on the priorities expressed by the AHIC workgroups. These high-level use cases focus on the needs of many individuals, organizations, and systems rather than the development of a specific software system. The use cases describe involved stakeholders, information flows, issues, and systems needs that apply to the multiple participants in these arenas.

The use cases strive to provide enough detail and context for detailed policy discussions, standards harmonization, certification considerations, and architecture specifications necessary to advance the national health information technology (HIT) agenda. These high-level use cases focus, to a significant degree, on the exchange of information between organizations and systems rather than the internal activities of a particular organization or system.

During the January 2007 AHIC meeting, nine priority areas (representing over 200 identified AHIC and AHIC workgroup detailed priorities) were discussed and considered. Three of these areas (Consumer Access to Clinical Information, Medication Management, and Quality) were prioritized and developed into the 2007 Detailed Use Cases, which were published in June 2007. The Health Information Technology Standards Panel (HITSP) Technical Committees are currently conducting harmonization work on these use cases.

The remaining six priority areas from the January 2007 AHIC meeting (Remote Monitoring, Remote Consultation, Personalized Healthcare, Referrals & Transfers in Care, Public Health Case Reporting, and Response Management) were updated based upon AHIC feedback and were reviewed during the July 2007 AHIC meeting. These six priority areas are now being developed into the 2008 Use Cases which will be processed in the national HIT agenda activities in 2008.

The 2008 Use Cases are being developed by the Office of the National Coordinator for Health Information Technology (ONC) with opportunities for review and feedback by interested stakeholders within both the private and public sectors. To facilitate this process, the use cases are being developed in two stages:

- The **Prototype Use Cases** describe the candidate workflows for the use case at a high level, and facilitate initial discussion with stakeholders; and

- The **Detailed Use Cases** document all of the events and actions within the use case at a detailed level.

This document is a prototype use case, which describes at a high level the actors, capabilities, and information sharing needs associated with this use case. ONC is publishing the prototype use case at an earlier stage of development in order to incorporate more substantive input from interested stakeholders into the detailed use case.

The prototype use case is divided into the following sections:

- Section 2.0, Introduction and Scope, briefly describes the priority needs identified by one or more AHIC workgroups and preliminary decisions made about the scope of the use case.

- Section 3.0, Use Case Stakeholders, briefly describes individuals and organizations which participate in activities related to the use case and its components.

- Section 4.0, Issues and Obstacles, briefly describes issues or obstacles which may need to be resolved in order to achieve the capabilities described in the use case.

- Section 5.0, Perspectives, briefly describes how the use case combines similar roles (or actors) in order to describe their common needs and activities. The roles are intended to describe functional roles rather than organizations or physical entities.

- Section 6.0, Candidate Workflows, briefly describes how various perspectives interact and exchange information within the context of a workflow. The use case workflow model provides a context for understanding the information needs and is not meant to be prescriptive.

- Appendix A, the Glossary, provides draft definitions of key concepts and terms contained in the prototype.

Also within the prototype document are specific questions for which ONC would like to receive feedback during the development process. Following receipt of feedback from interested stakeholders, ONC will develop a detailed use case, which will incorporate the feedback received, fully describe the events and activities from a variety of perspectives, and include information flow diagrams.

2.0 Introduction and Scope

In July 2007, AHIC approved a recommendation to develop a use case that addresses the exchange of information supporting the distribution and administration of medication, vaccination and other specific medical prophylaxis and treatment methods. This use case will focus on the ability to communicate a subset of relevant information about needs for medication and prophylaxis resources, about resource availability, about their administration and about the status of treated and immunized populations. Resource information includes the support of the routine delivery system and needs that build upon the routine processes and systems to support emergencies. Supplemental information for emergencies can include both emergency resources (such as the national stockpile) and information flows (such as the support of the apportionment of a limited resource in an emergency).

AHIC prioritized needs related to this use case include:

- The ability to exchange information about the need to administer resources, the availability of resources and their actual administration (including isolation and quarantine) is critical to coordinating response activities and managing available medical resources during a public health emergency.

- The integration of supply chain information from public and private sectors will provide data to support informed decision making as well as support response and treatment activities.

- Automated integration with related registries, such as immunization registries, registries of emergency response volunteers, registries of individuals given other prevention and treatment interventions, and registries supporting long-term follow-up will support case management activities.

To achieve this, the Immunizations and Response Management Prototype Use Case focuses on: 1) access to information about individuals who needs to receive specific resources; 2) the ability to exchange specific resource and supply chain data from public and private sectors; 3) the ability to track and manage administration of prevention and treatment interventions, including isolation and quarantine; and, 4) the ability to identify and electronically exchange information describing the status of populations relative to having received treatment or prophylaxis. This prototype use case will describe these activities within the context of two candidate workflows:

- **Resource Availability and Need.** Information regarding the location and availability of resources is collected and exchanged to allow for coordinated delivery of care.

- **Treatment and Intervention.** The identification of individuals with needs and the administration of prevention and treatment interventions. Supply of data to and from appropriate registries to support clinical and Public Health follow-up activities. Information regarding isolation/quarantine status is used to determine status and needs of affected individuals.

This use case assumes the developing presence of electronic systems such as electronic health records (EHRs), Personal Health Records (PHRs), and other local or Web-based solutions supporting consumers and clinicians, while recognizing the issues and obstacles associated with these assumptions. This approach helps promote the development of longer-term efforts.

3.0 Use Case Stakeholders

Figure 3-1. Immunizations & Response Management Use Case Stakeholders Table

Stakeholder	Working Definition
Clinicians	Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, and other credentialed personnel involved in treating patients.
Commercial Sector Supply Chain	Entities involved in the production, storage, and distribution of medication and immunization products at the community, regional, and national level, such as pharmaceutical manufacturers, drug wholesalers, and community pharmacies.
Consumers	Members of the public who may receive healthcare services. These individuals may include: caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient in the activities of receiving healthcare.
Healthcare Entities	Organizations that are engaged in, or support the delivery of, healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health, school health, dental clinics, psychology clinics, care delivery organizations, and other healthcare facilities.
On-site Care Providers	Police, Fire, Emergency Medical Technicians (EMTs), and other medically trained emergency responders who provide care while at, or in the transport from, the site of an emergency.
Patients	Members of the public who receive healthcare services.
Public Health Agencies (local/state/federal)	Local, state, and federal government organizations and personnel that exist to help protect and improve the health of their respective constituents.
Registries	Organized systems for the collection, storage, retrieval, analysis, and dissemination of information on individual persons to support health needs.
Resource Managers	Individuals who are responsible for coordinating resources to support the delivery of care. These individuals determine the needs and coordinate logistics to support the delivery of care.

ONC would like to receive feedback on the draft list of stakeholders and their descriptions for this use case. Please suggest additions, deletions and/or revisions to the description of the stakeholders.

4.0 Issues and Obstacles

Realizing the full benefits of Immunizations and Response Management will be dependent on overcoming a number of issues and obstacles in today's environment. Inherent in this use case is the premise that some of these issues and obstacles will be addressed through policy development, HIT standardization and harmonization activities, health information exchange (HIE) networks and other related initiatives.

- Response plans and memorandum of agreements at the state and local level are inconsistent, which affect the degree to which information can be shared and aggregated efficiently.

- Data exchange may be hampered by the proprietary nature of some business information, a lack of harmonization of the data sets needed to support response management, including the underlying data definitions, the minimum data required; an inconsistent implementation of existing data standards.

- There are likely to be varying levels of technical infrastructure available to those participating in an emergency response situation.

- A lack of widespread EHR adoption combined with limited integration of EHRs with public health activities, as well as a lack of EHR decision support to prompt for immunization reminders and prevention guidelines may limit the full realization of the electronic management of prevention and treatment intervention methodologies for routine and emergency situations.

- During a shortage or emergency, the availability of resources must be ascertained from multiple disparate sources. Today, the private sector supply chain and stockpile information are not integrated, which is critical to coordinating response activities and managing available medical resources during a public health emergency.

ONC would like to receive feedback on the draft list of issues and obstacles and their descriptions for this use case. Please suggest additions, deletions and/or revisions.

5.0 Use Case Perspectives

The Immunizations and Response Management Prototype Use Case will describe prophylaxis and treatment access, administration and tracking from the viewpoints associated with at least four perspectives. The perspectives included in the use case are intended to indicate roles and functions, rather than physical locations. Each is described below:

- **Consumer**

The consumer perspective includes individuals who need or have received prevention and treatment interventions such as immunizations.

- **Public Health**

The public health perspective includes entities, such as local, state, and federal government organizations, that provide guidance on determining and fulfilling the needs of the public, as well as providing some of the medication and vaccination and support resources and frequently track those who have received them in routine (vaccination) and emergency contexts.

- **Resource Manager**

The resource manager perspective includes different individuals who are responsible for coordinating resources in the commercial and public health supply chain to support access and delivery. These individuals coordinate needs with available resources to support the needs of administration.

- **Clinician**

The clinician perspective includes healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, and other credentialed personnel involved in administering to and treating patients. Clinicians provide prevention and treatment interventions and supervise the documentation of administration information and report relevant information.

These perspectives are the focus of the events described in the following candidate workflows.

ONC would like to receive feedback on the draft list of perspectives and their descriptions for this use case. Please suggest additions, deletions and/or revisions.

6.0 Candidate Workflows

The Immunizations & Response Management Prototype Use Case candidate workflows model the exchange of information between different entities that store data related to resource and supply chain information from public and private sectors, relevant registries, and appropriate case/event reporting and EHR systems. The candidate workflows describe roles which may be fulfilled in several different settings during routine activities while being supportive for emergency situations. The workflows indicated are not intended to be comprehensive or limiting.

6.1 Resource Availability and Need

This candidate workflow focuses on the ability to electronically communicate a subset of relevant information about individuals who need medication, prophylaxis and treatment resources, information about resource availability and information about the administration of these resources. Information regarding the location and availability of resources is collected and aggregated to allow for coordinated delivery of care.

- Populations with needs in accordance with routine needs, emergency exposures, specific role or medical status are conveyed from clinical care, registries or public health.

- The resource manager distributes reporting specifications. The resource manager inventories resources. The resource manager accesses information describing the availability of response resources from several disparate sources.

- Information could be gathered electronically from the commercial sector supply chain as well as emergency supplies.

- The resource manager orders and acquires resources. The resource manager mobilizes resources based on need and availability. The resource manager tracks and communicates resource status.

6.2 Treatment and Intervention

This candidate workflow focuses on the administration of prevention and treatment interventions and the management of patients in isolation and quarantine. At a high level,

the following needs have been identified, and will be included in this candidate workflow:

**Figure 6-1. Response Management: Treatment & Intervention
Workflow Summary**

	Prevention (e.g. routine vaccinations, immunizations and prophylaxis)	**Treatment** (e.g. medication)	**Isolation and Quarantine**
Identification	▪ Identify target population	▪ Identify target population	▪ Identify target population
Availability	▪ Gather and distribute prevention interventions	▪ Gather and distribute treatment interventions	▪ Identify isolation and quarantine locations
Administration Status	▪ Administer the intervention ▪ Report administration to relevant registry as appropriate	▪ Administer the intervention ▪ Report administration to relevant registry as appropriate	▪ Assign patients to locations ▪ Record relevant clinical, and logistical information into relevant registry
Post-Intervention Follow-up Activities	▪ Conduct activities including clinical confirmation of successful administration and adverse event detection	▪ Conduct activities including clinical confirmation of successful administration and adverse event detection	▪ Conduct activities including clinical symptom detection and identification of additional resource needs (e.g. food for home quarantine)

This scenario additionally focuses on access to aggregated data from appropriate registries to notify Public Health to conduct follow-up activities, as well as the ability to exchange information regarding isolation/quarantine status to determine status and needs of affected individuals.

- The consumer inputs information regarding immunizations received into their PHR.

    o This information could be available to a clinician via retrieval from the consumer's PHR, or provided automatically to the clinician based on the consumer's preferences.

ONC would like to receive feedback on whether or not potential exists for self-reported immunization information to play a role in populating immunization registries or EHRs, assuming the information source (e.g., authoritative clinical source, administrative source, or patient) has been captured.

- Public health gathers immunization status of individuals and identifies target population to receive prevention and treatment interventions.

    o Public health determine target population(s) based on clinical inputs from disparate sources. This includes population health information from federal, state and local health authorities.

- The clinician gathers patient information.

    o The clinician gathers consumer self-reported data and additional
      information from other disparate sources (such as electronic medical
      records (EMR) systems, EHRs, registries, etc.)

- The clinician administers the intervention.

    o Based on clinical indicators, the clinician administers the appropriate
      prevention or treatment intervention.

    o For isolation and quarantine, patients may be assigned to locations.
      Relevant clinical and logistical information is reported to the relevant
      registries.

- The clinician provides information to next provider of care.

    o The clinician provides prevention and treatment intervention
      administration and immunization information to the next provider of care
      and relevant registry.

    o This includes immunization status and allergy information, as well as data
      sets of immunization information contained within a registry (e.g., to
      support query/response transactions initiated by a public health entity –
      such as a request for a list of all persons immunized within a given period
      of time utilizing a specific vaccine.)

- The clinician provides specific information to public health agency based on
  requirements.

    o The clinician reports relevant clinical information based on active
      surveillance requirements set forth by public health.

    o Public health analyzes data gathered from to determine appropriate
      follow-up activities.

o   Based on need, the status and needs of individuals who have been
    isolated or quarantined is communicated.

*ONC would like to receive feedback on these candidate workflows. Based on the
steps outlined above for inventorying, ordering, and mobilizing resources, would
information needs that support the delivery of care during routine clinical care,
change during emergencies? Should any changes be made to the descriptions of
these interactions? Are the needs related to routine immunization activities
adequately described?*

*For those candidate workflows listed, is the working definition of key information
sources and recipients sufficient? If not, what changes should be made?*

Appendix A: Glossary

AHIC: American Health Information Community.

Care: Relieving the suffering of individuals, families, communities, and populations by providing, protecting, promoting, and advocating the optimization of health and abilities.

CCHIT: Certification Commission for Healthcare Information Technology.

Clinicians: Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, and other credentialed personnel involved in treating patients.

CMS: Centers for Medicare & Medicaid Services, a federal agency within the Department of Health and Human Services.

Commercial Sector Supply Chain: Entities involved in the production, storage, and distribution of drug products at the community, regional, and national level, such as pharmaceutical manufacturers, drug wholesalers, and community pharmacies.

Consumers: Members of the public who may receive healthcare services. These individuals may include: caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient in the activities of receiving healthcare.

Department of Health and Human Services (HHS): This is the federal agency responsible for human health, and has oversight over many other federal agencies such as FDA, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), CMS, the Agency for Health Research and Quality (AHRQ), the Substance Abuse and Mental Health Services Administration (SAMHSA), and others.

Electronic Health Record (EHR): The electronic health record is a longitudinal electronic record of patient health information generated in one or more encounters in any care delivery setting. This information may include patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory information and radiology reports.

FDA: Food and Drug Administration.

Health Information Exchange (HIE): A multi-stakeholder entity that enables the movement of health-related data within state, regional, or non-jurisdictional participant groups.

Healthcare Entities: Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health, school health, dental clinics, psychology clinics, care delivery organizations, and other healthcare facilities.

HITSP: Healthcare Information Technology Standards Panel.

ONC: Office of National Coordinator for Health Information Technology.

On-site Care Providers: Police, Fire, Emergency Medical Technicians (EMTs), and other medically trained emergency responders who provide care while at, or in the transport from, the site of an emergency.

Personal Health Record (PHR): A health record that can be created, reviewed, annotated, and maintained by the patient or the caregiver for a patient. The personal health record may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history, or communications with healthcare providers.

Point-to-Point Exchange: A direct link or communication connection with defined endpoints.

Public Health Agencies (local/state/federal): Local, state, and federal government organizations and personnel that exist to help protect and improve the health of their respective constituents.

Resource Managers: Individuals who are responsible for coordinating resources to support the delivery of care. These individuals determine the needs and coordinate logistics to support the delivery of on-site care.